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EXPLAINER

Summer 2023: Trends in Nicotine & Tobacco Harm Reduction Research

July 2023

Introduction

The world of tobacco harm reduction science and regulation is changing at a rapid pace. With all the new and conflicting information out there, keeping up is difficult and time consuming. Here, we summarize some of the recent stories in this space with the aim of sparking new conversations that will help to reframe the debate so that real harm reduction opportunities can continue to grow and become a reality for consumers.

1 Incoming Results – The Memory Improvement through Nicotine Dosing (MIND) Study

This study will determine if nicotine has the potential to benefit brain health and improve cognitive function both immediately and over long-periods of time.

The MIND study is currently ongoing and is one of the largest randomized clinical trials ever conducted to measure how nicotine use impacts several measures of cognitive function and memory. Its design is based on a 2012 pilot study in which researchers were able to determine that over a 6-month period, those that used a nicotine patch performed significantly better on cognitive performance tests than those that received the nicotine-free patches.

The MIND study has the potential to greatly improve our understanding of age-related cognitive decline. Additionally, the data from this study provides detailed health data related to nicotine use and identifies associated risks that may occur due to long-term use. The MIND study is slated to close in July 2023 and, once the data is analyzed and published, we'll have a clearer picture of the potential health benefits and risks of nicotine use.

2 Food and Drug Administration (FDA) UPDATE – PMTA Progress

In order to market and sell a tobacco or non-pharmaceutical nicotine product in the United States the product must go through one of several review pathways and be authorized by the FDA Center for Tobacco Products (CTP). For most reduced risk products, such as electronic nicotine delivery systems (ENDS), heat-not-burn and modern oral products, the pathway is through the Premarket Tobacco Product Application (PMTA). The FDA-CTP set a mandate that in order for any new (developed prior to 2016) tobacco/nicotine product to stay on or enter the U.S. marketplace, the manufacturer of the product must submit a PMTA application to the FDA-CTP by Sept. 9, 2020. The FDA-CTP was mandated by law to complete the review of all applications within a year of receipt.

The FDA-CTP reported that they received nearly 6.7 million applications. Clearly the review of this mountain of work would require more than a year to complete, and it has. As of June 2023, the FDA-CTP has reported that they have completed nearly 99 percent of the reviews and only have 1 percent remaining. **Let's look into their numbers a bit more deeply.**

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These challenges emphasize the importance of the revision and refining of the PMTA. There are several opportunities for improvement in the PMTA process that will greatly enhance the regulation of tobacco and nicotine products.

The take-home messages that the FDA-CTP, manufacturers and consumers should pay attention to are as follows:

- **The process is not clear.** The overwhelming majority of the applications were not reviewed based on the science; instead they were refused or not filed due to missing attributes or sections.
- **The necessary information for an application is not well defined.** The FDA-CTP published a guidance document in 2021 which sets forth the expected contents of a PMTA. Even with this document guiding manufacturers, the overwhelming majority of applications were deemed unfit to review.
- **Only 31 reduced risk products have been awarded a marketing order and well over a million applications have received a marketing denial order.** The FDA-CTP budget is nearly $700 million dollars per year and tobacco and nicotine product manufactures have reported that a single PMTA application could cost the manufacturer millions of dollars. The amount of money and time spent to have only 31 products reach the standard that the FDA-CTP has outlined suggests that there are problems with the process.

These challenges emphasize the importance of revising and refining the PMTA. There are several opportunities for improvement in the PMTA process that will greatly enhance the regulation of tobacco and nicotine products—from clarifying the application process to clearly articulating the research requirements and best practices observed in successful applications.

3 Latest trends in Youth Cigarettes / Nicotine Product Use

The use of any nicotine product by individuals under the age of 21 should be discouraged and effective education measures (through community leaders and parenting strategies) should be in place to help lower youth tobacco and nicotine use. However, we must be clear on the need to balance providing reduced risk products to support adult consumers as they transition from combustible cigarettes to alternatives.

There are several surveys administered each year to track the use of tobacco and nicotine products by underage consumers. These include the National Youth Tobacco Survey (NYTS), Monitoring the Future (MTF), the National Health Interview Survey (NHIS) and the Population Assessment of Tobacco and Health (PATH).

A recent publication has attempted to generate a holistic analysis of these surveys to generate a better understanding of the overall trends in underage tobacco and nicotine product use.

The researchers' analysis of the data suggests that since 2012 there have been two general trends. The first is a decrease in high school aged students currently (past 30 days) using combustible products, from 13.2 percent in 2012 to 1.9 percent in 2021. The second is an overall increase in the current use of ENDS products, from 2.7 percent in 2012 to a high of 27.3 percent in 2019. Then

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dropping to 11.2 percent in 2021. In general, the take-home message is that though the use of ENDS products has increased, there is an immense reduction in the use of combustible cigarettes among high school aged students. These trends are reflected in the other surveys as well.

As always, underage use should continue to be monitored and any new use patterns and potential health risks identified.

4 Consequences of Prohibition

As the FDA-CTP plans to enact a prohibition on menthol cigarettes and flavored cigars, it is important to consider the potential consequences of such action on consumers and the communities in which they reside. Several states have promoted legislation that would restrict the sale of flavored (including menthol) tobacco and nicotine products. Massachusetts was the first to do so in 2019, and California the most recent, in 2022.

Massachusetts provides yearly reports on how their restrictions have impacted the illegal use of the banned products and the citizens of their state. However, the data from the Massachusetts reports does not tell the entire story. A recent publication suggests that though tobacco product sales were down in Massachusetts, the counties of the bordering states had significant increases in sales of the banned products. The results suggest that if you consider the state in isolation, sales in Massachusetts dropped by just over 29 million packs. However, if you add the bordering states into the count, the numbers increased to over 33 million additional packs, suggesting a million pack increase in product sales in the region and no associated change in tobacco and nicotine product use.

In California, the law is too new to quantify details at the level of what is seen in Massachusetts, but early numbers suggest that things are trending in the same direciton. Data from January 2020 compared to the same month for 2023 suggests a limited decline in sales (17.3 percent) in the state and is predicted to exceed a loss of over $300 million in sales for the year. The new law also increased the flow of illicit products into the state.

Probably the biggest take home message is that when over-regulation enters, criminal activity increases. Regardless of the financial consequences, the overreaching attempt to control human behaviors through legal restraints rarely, if ever, benefits the individuals most directly affected by these sociological experiments. Tobacco harm reduction policies, with clear and science-based education, incentivize the switch to reduced risk products and allow the individual the ability to make their own choices, which leads to changes without criminalizing a subset of our population. As the FDA-CTP ponders similar actions at the federal level, they should recognize these potential risks and consider moving forward carefully by supporting pathways to harm reduction as suggested by experts that have been working on how to solve the combustion problem for decades.

Contact us

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